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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,516	HAMMOND ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-75* is/are pending in the application.

4a) Of the above claim(s) *1-44 and 51-71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-50 and 72-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3-8-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group III (methods of removing prions from a biological fluid using either 1) a polypeptide ligand to a prion, or 2) an amino resin) in the reply filed on March 8, 2005 is acknowledged.

2. Claims 1-44 and 51-71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 8, 2005.

3. Currently, claims 45-50, and 72-75 are pending and under consideration.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on March 8, 2005, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

5. The following reference is in a foreign language accompanied by an English abstract. Due to this, the reference has been examined only to the extent of the disclosure in the abstract.

WO 99/15651.

Priority

6. It is noted that the Applicant appears to have intended to claim priority to earlier filed application 09/543,188. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. This reference must be submitted during the pendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C. 111(a), this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed application. If the later-filed application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, this reference must also be submitted within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371 (b) or (f) in the later-filed international application or sixteen months from the filing date of the prior-filed application. These time periods are not extendable. Except as provided in paragraph (a)(3) of this section, the failure to timely submit the reference required by 35 U.S.C. 120 and paragraph (a)(2)(i) of this section is considered a waiver of any benefit under 35 U.S.C. 120, 121, or 365(c) to such prior-filed application.

A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional.

It is noted that if the Applicant claims such benefit in a manner not recognized under 37 CFR 1.78(a), but such a claim was recognized in the filing receipt, the Applicant will not be required to submit a petition for delayed claim of priority, but is still required to amend the specification to refer to the earlier filed application.

Specification

7. The use of the trademark TOYOPEARL® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

8. Claim 45 is objected to because of the following informalities: it appears that line 3 of subpart a) of the claim should read on ligands - - wherein said ligand is less than about 6 kDa...- - Appropriate correction is required.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 45-50 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility. This rejection is based on an assumption that the claim is intended to read on a peptide comprising a retro-inverso isomer of SEQ ID NO: 1. In such a case, the applicant has not provided a utility for the claim, because although the applicant does discuss retro-inverso isomers in the specification, the applicant has not stated or described any naturally occurring, or other, proteins or polypeptides that comprise the sequence of such isomers.

The claims are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 47 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the limitation "wherein said peptide ligand." There is insufficient antecedent basis for this limitation in the claim. Claim 45, from which this claim depends, reads on ligands generally, and is not limited to peptide ligands.

13. Claims 48-50 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 48 is treated as representative of the rejected claims. This claim reads on a method of removing a prion from an environmental sample comprising contacting the sample with a prion "in said biological fluid." There is insufficient antecedent basis for this limitation in the claim because the claim provides no antecedent basis for the phrase "said biological fluid." It is unclear what biological fluid is being referred to.

Because it appears that the Applicant intended that the claim refer to - - said environmental sample- - instead of "said biological fluid," the claim will be read as though such was the case for the purposes of this action.

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 45-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make, and/or use the invention. The claims are drawn to methods of removing prions from samples comprising the use of a ligand that is "less that about 6 kDa and binds to a polypeptide comprising the amino acid sequence GWGQPHGG (SEQ ID NO: 1)."

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered. In the present case, the factors deemed relevant are those of the amount of direction and the working examples provided, that quantity of experimentation necessary, the (un)predictability of the art, and the breadth of the claims.

As indicated above, the claims are broadly drawn to ligands of the sequence disclosed as SEQ ID NO: 1, and to any polypeptide comprising such a sequence (i.e. the ligand need not bind to this sequence so long as the polypeptide to which the ligand binds comprises SEQ ID NO: 1 somewhere within its sequence). In support of this claim, the application has identified a number

of peptide ligands that have been identified as binding to SEQ ID NO: 1, and provided methods for screening for other such ligands. See e.g., application pages 5-6, and 10-11. However, it is noted that there does not appear to be any common structure among the various identified peptide ligands, and the application provides no examples of any non-peptide ligands. Thus, the application provides only limited guidance towards the identification of either peptide or non-peptide ligands other than the peptides disclosed in the application. This is because the application provides no means by which those in the art may accurately predict whether any particular compound would be capable of acting as a ligand for the indicated sequence. There is no identification of a shared structure or element by such ligands, or any other means of determining what other molecules would be likely ligands. Because the claims read on methods of using any prion ligand that binds to the indicated sequence, in view of the large numbers of potential compounds available for screening for such activity, and in view of the lack of any means of predicting whether any specific peptide or other molecule would have the required function, the application does not enable those in the art to practice the claimed invention to the full extent as claimed.

16. Claims 45-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejected claims have been described above. They read on a genus of methods

comprising the use of any prion ligand of less than 6 kDa and that binds to a polypeptide comprising SEQ ID NO: 1, or polypeptide ligands meeting these limitations.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed.

In the present case, the claims are drawn to methods of using either a genus of any ligand, or of using any peptide ligand, that meets the requirements of being less than about 6 kDa, and having the required binding activity.

With respect to the first, more general, genus comprising any prion ligand, it is noted that the application has provided some examples of peptide ligands meeting the indicated requirements. However, the identification of these peptide ligands provides very little if any descriptive support for non-peptide ligands that may be used in the claimed methods. The identification of these peptide ligands therefore fails to provide a sufficient number and variety

of ligand species to support claims drawn to methods of using any prior ligand meeting the indicated limitations.

The claims appear to attempt to remedy this lack of support by providing both structural (weight limitation) and functional (target polypeptide binding) requirements for the genus of ligands that may be used. However, as described above, the Federal Circuit has noted that when the genus is being identified by a function in combination with a structure, there must be some correlation between the structure and function. No such correlation has been demonstrated in the present case. Thus, the claims are drawn to methods of using ligands with two identified features, neither one of which alone provides sufficient information to allow those in the art to distinguish those molecules that fall within the class of ligands that may be used in the claimed methods from those that do not. Further, because there is no known or established relationship between the indicated function and structure, the identification of these features in combination also fails to provide adequate written description for the claimed genus.

With respect to claims limited to the use of polypeptide ligands, it is noted that the application provides examples of several potentially useful peptide ligands. However, even the presence of multiple species with in a claimed genus does not necessarily demonstrate possession of the genus. See, In re Smyth, 178 U.S.P.Q. 279 at 284-85 (CCPA 1973) (stating "where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus or combination claimed at a later date in the prosecution of a patent application."); and University of California v. Eli Lilly and Co., 43 USPQ2d 1398, at 1405 (Fed Cir 1997)(citing Smyth for support). In the present case, it is noted that there does not appear to

be any common structural element to the various identified peptide ligands. Thus, one of ordinary skill in the art looking at these peptides would have no clear means of identifying other peptides that would be likely to have the required functional activity. I.e., there is no certainty as to which other peptides than those specifically disclosed would also have the required function. Because the application neither provides sufficient polypeptide ligand species to demonstrate the possession of all peptide ligand species, and because the application has identified no common structural characteristic that correlates with a peptide's ability to act as a prion ligand, the application also fails to provide adequate written description support for any peptide ligand that may be used in the indicated methods.

17. Claims 72-75 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of removing prions from a sample using the Toyopearl 650 M amino resin, does not reasonably provide enablement for methods of using any amino resin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The claims read on methods of removing prions from a sample by contacting the sample with an amino resin.

The factors to be considered in making a determination as to enablement have been described above. In this case, the relevant factors to be considered are the number of examples provided, the scope of the claims, and the guidance presented in the application.

In the present application, the application has demonstrated only a single instance where an amino resin was capable of binding to prions in a sample. See e.g., page 29. However, there is

no identification of characteristic of the amino resin responsible for its prior binding activity such that those in the would be able to identify other amino resins capable or performing this activity. Nor does the application demonstrate that any other amino resin would be useful in the claimed methods. Thus, although the claims are broadly drawn to methods of using any amino resin, the teachings of the application are limited to a specific resin, and provide no guidance towards other amino resins that would be useful in the claimed methods.

It is noted that the art does not provide many teachings about the use of unmodified resins for the specific capture of prions. However, one reference (Carbonell et al., U.S. 2005/0014196) does provide teachings indicating that not every resin would be useful in the claimed methods. See e.g., pages 9-11 (Table I- showing that some resins do, and others do not, bind prions). In particular, while the reference supports the teachings of the present application with respect to the Toyopearl® 650M amino resin, other amino resins disclosed in the reference did not bind to prions. See e.g., Page 10, Reference 46 (teaching that the E. Merck Fractogel ® EMD Amino resin was not effective for bind prions). In view of these teachings indicating that not every amino resin would be capable of use in the claimed methods, and in view of the limited teachings in the present application providing guidance to amino resins that would be so useful other than the single embodiment disclosed, the application has not provided sufficient information to enable those in the art to practice the claimed method to the full extent.

In case the Applicant amends the claims to limit it to the use of the specific amino resin identified in the application, the Applicant's attention is directed to MPEP § 2173.05 (u). This section of the MPEP notes that if a tradename is used in claim "to identify or describe a

particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph." The MPEP explains that, in such cases the "the claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product."

18. Claims 72-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims have been described above. They read on a genus of methods of using any amino resin for the removal of prion proteins from samples. The requirements for providing written description support for a genus of inventions have been described above.

In the present instance, the application provides only a single working example of the claimed methods. Further, the application does not demonstrate that any amino resin would be capable of performing in the claimed methods, or provide any identification of a structural feature of amino resins that would be useful in methods for the removal of prions from a sample (i.e. no correlation of any structure with the prion-binding activity required). In view of the presence of only a single example, the lack of any demonstration that any amino resin would be useful in the claimed methods, and the lack of identification in the application of any structure by which those in the art could identify other amino resins with the required function, the application does not provide adequate support for the full scope of the claimed genus of methods.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

20. Claims 45 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Pruisner et al. (U.S. 6,221,614- of record in the March 2005 IDS). The claims have been described above. Pruisner teaches methods of separating prions from a sample comprising contacting the sample with ligand (phosphotungstic acid) to prion proteins (i.e. proteins comprising SEQ ID NO: 1) and separating the prions from the sample (or the substrate on which the prions are bound from the sample). See e.g., claims 1-4, and 6. The reference therefore anticipates the indicated claims.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. Claims 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Pruisner (U.S. 6,221,614) as applied against claims 45 and 46 above, further in view of the teachings of any of Soto-Jara et al. (WO 96/39834), or Pruisner II (U.S. 5,750,361). Claims 45 and 46 have been described above. Claim 47 appears to further require that the ligand is a peptide of less than 6 kDa.

Soto-Jara teaches two peptides disclosed as capable of binding to prion proteins (pages 16-17), and teaches that these peptides may be used for the detection of the target protein (page 20). Pruisner II also teaches peptides that are disclosed as binding to prions. See e.g., column 7, lines 55-65. It would therefore have been obvious to those in the art that the peptides of Soto-Jara or Pruisner II could be substituted for the ligands disclosed in the Pruisner reference in the methods for removing prions. This is because the Soto-Jara reference teaches that the peptides are effective ligands for binding prions, and would therefore be functional equivalents of the compounds disclosed in Pruisner. Because the teachings of Pruisner indicate that any ligand may be used in the methods disclosed therein, those in the art would have had a reasonable expectation of success in making the substitution.

23. Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pruisner in view of Soto-Jara and Pruisner II as applied to claims 45-47 above, and further in view of Hammond et al., WO 00/02575. These claims read on methods substantially similar to those of claims 45-47 except that the samples in these claims are "environmental" samples, and include soil samples. While the three previously cited references render obvious the use of peptide ligands for the removal of prions from biological samples, they do not appear to teach the

removal of prions from environmental samples. However, such teaches are provided by the Hammond reference, which indicates that prions may be found in such environmental samples. See e.g., claim 37. It would therefore have been obvious to those in the art that the methods of Pruisner, using the peptides of Soto-Jara and Pruisner II, could be used to remove prions from environmental samples. The combined teachings of the references therefore render the claimed methods obvious.

24. Claims 72-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pruisner or Pruisner in view of Soto-Jara, Pruisner II, and Hammond as applied against claims 45-50 above, and further in view of Kragten et al., J Biol Chem 273: 5821-28. These claims read on methods of removing prions from samples comprising contacting the prions with an amino resin. It is noted that the claims do not require that the prion must interact directly with the amino resin, or that the amino resin is not also complexed with a ligand for prions. Thus, the claims read on any method of removing prions from a sample, wherein the sample is contacted with a amino resin.

The teachings of Pruisner, Soto-Jara, Pruisner II, and Hammond have been described in part above. The references teach a method for the separation of prions from a sample comprising contacting the sample with a ligand complexed with a substrate. Although the Pruisner reference provided several examples of purification techniques, the reference does not specifically teach the use of an amino resin. See e.g., column 12, lines 25-29. However, from these teachings, it would be clear to those in the art that any known purification technique could be used.

Kragten teaches a method for affinity precipitation of a compound through attaching a ligand of the compound to an amino resin (Toyopearl AF amino 650 M resin), and contacting a

sample comprising the target with the ligand immobilized on the resin. See e.g., page 5822 (3rd paragraph under Experimental Procedures). The teachings of this reference demonstrate that the amino resin is a known substrate for use in affinity based separation of compounds from samples. Thus, it would have been obvious to those in the art that the amino resin of Kragten was a functional equivalent of the matrices disclosed in the affinity chromatography example (column 12) of the Pruisner reference. It would therefore have been obvious to those in the art to substitute the amino resin of Kragten as the substrate used in the purification techniques disclosed by the Pruisner. The combined teachings of these references therefore render the claimed methods obvious.

25. Claims 72-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al., U.S. 6,750,025. As indicated above, these claims read on methods of removing prions from samples comprising contacting the prions with an amino resin. It is noted that the claims do not require that the prion must interact directly with the amino resin, or that the amino resin is not also complexed with a ligand for prions. Thus, the claims read on any method of removing prions from a sample, wherein the sample is contacted with a amino resin.

The Hammond reference identifies a ligand for prions (streptavidin). Claim 1. The reference also teaches that the identified ligand may be used either for the detection of prions, as was claimed in the patent, or for the removal of prions from a sample. Column 2, lines 63-67. As a means for carrying out the invention, the reference teaches that the ligand may be attached to a affinity column formed on a resin, including on Toyopearl resins. Column 5, lines 6-17. The reference further identifies a Toyopearl amino 650 M resin as a Toyopearl resin. Column 10,

lines 44-46. It would therefore have been obvious to those in the art to remove prions from a sample by attaching a ligand, including streptavidin, to the indicated Toyopearl ® amino resin and contacting the resin with the sample. The teachings of the reference therefore render the claimed invention obvious.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Double Patenting

26. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

27. Claim72-75 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 13, 18, 22, and 23 of copending Application No. 10/817,117. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are generic to the present claims, but the limitations of the present claims are either inherent to (i.e. removal of the prions from the sample) the copending claims, or the limitations (i.e. claim 75) are described in those portions of the specification providing support for the copending claims. See e.g., pages 8-9, paragraph [0085] (teaching sources from which the prions may be removed). The present claims are therefore obvious variations of the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

28. The above rejection is, in part, based on the specification of a previously issued patent, rather than the claims. In support of the use of this material, the examiner notes the following excerpt from MPEP section 804 II(B)(1):

> When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.
>
> The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is based. This is true even where elements are drawn from the specification describing the claimed invention which are not elements in the claim itself.

Conclusion

29. No claims are allowed.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

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